

REMARKS

Claim 89 is pending in the subject application. No claim has been added, canceled or amended herein. Accordingly, claim 89 is still pending and under examination.

In view of the arguments set forth below, applicant maintains that the Examiner's rejections made in the April 17, 2002 Office Action have been overcome and respectfully requests that the Examiner reconsider and withdraw same.

Rejection Under 35 U.S.C. §101

The Examiner rejected claim 89 under 35 U.S.C. §101 as allegedly not supported by a specific and credible utility.

In response, applicant respectfully traverses the Examiner's rejection. In support of applicant's traversal, applicant incorporates herein by reference his remarks set forth in the September 17, 2001 Amendment in response to the rejection under 35 U.S.C. §101. Applicant also sets forth the following remarks to underscore his position, and to address the Examiner's additional remarks in the April 17, 2002 Office Action.

Claim 89 provides an isolated human MUM-1 (also referred to as "MUM1") protein or a fragment thereof. In this application, applicant establishes that over-expression of the MUM-1 gene (i.e., over-production of MUM-1 mRNA) correlates with multiple myeloma. Applicant maintains that absent a showing to the contrary, one of skill would reasonably conclude that over-production of MUM-1 protein

would accompany over-production of its corresponding mRNA.

The Examiner asserts that such correlation between protein over-production and mRNA over-expression would not reasonably be expected. The Examiner cites Anderson, et al. in support of this position.

Applicant maintains that the Examiner has misconstrued the teaching of this reference. That is, Anderson et al. in fact support applicant's position that a positive correlation would reasonably be expected between mRNA and protein over-expression.

Anderson, et al. determine the correlation between the over-expression of 19 human liver proteins and the over-expression of their corresponding mRNAs. The correlation determined for these 19 protein/mRNA pairs was 0.48 (page 535, first column). On the scale used by Anderson, et al. where 1.0 represents a perfect correlation and 0.0 represents no correlation (page 536, first column), the observed correlation of 0.48 represents a positive correlation indeed. Applicant therefore maintains that this reference teaches a positive correlation between mRNA and protein over-expression.

Applicant notes the Examiner's statement that "one in the art would not assume that nucleic acid expression and protein expression are *parallel*" (emphasis added). Applicant is unclear what the Examiner means by "parallel" but, nevertheless, stresses that a positive correlation between mRNA and protein over-expression would be expected based on the teaching of Anderson, et al.

In view of Anderson, et al., applicant maintains that MUM-1 protein over-expression would *reasonably be expected* to correlate with multiple myeloma, based on the observed correlation between disease state and MUM-1 mRNA over-expression. The mere *possibility* that no correlation between MUM-1 protein over-expression and disease exists is insufficient to support the Examiner's rejection.

For these reasons and those set forth in the September 17, 2001 Amendment, applicant maintains that the claimed protein has a specific and credible utility.

In view of the above remarks, applicant maintains that claim 89 satisfies the requirements of 35 U.S.C. §101.

Rejections Under 35 U.S.C. §112, First Paragraph

The Examiner rejected claim 89 under 35 U.S.C. §112, first paragraph, as allegedly not enabled by the specification. The Examiner also rejected claim 89 under 35 U.S.C. §112, first paragraph, as allegedly not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor, at the time the application was filed, had possession of the claimed invention. The Examiner's rejections are based on the Examiner's assertions set forth in support of the rejection under 35 U.S.C. §101 above.

In response, applicant respectfully traverses the Examiner's rejections for the reasons set forth above in response to the rejection under 35 U.S.C. §101.

In view of the above remarks, applicant maintains that claim 89 satisfies the requirements of 35 U.S.C. §112, first paragraph.

Objection Under 35 U.S.C. §132

The Examiner objected to applicant's September 17, 2001 Amendment under 35 U.S.C. §132 as allegedly introducing new matter into the disclosure. Specifically, the Examiner asserted that the phrase "a fragment thereof" recited in claim 89 with respect to a MUM-1 protein, constitutes new matter.

In response, applicant respectfully traverses the Examiner's objection, and maintains that support for the phrase "a fragment thereof" is found at, *inter alia*, Figure 7, which shows the genomic organization of the MUM-1 gene. Specifically, Figure 7 shows MUM-1-coding regions indicated by filled boxes, each such coding region constituting a portion, i.e., a *fragment*, of a complete MUM-1 protein. Similarly, Figure 12B shows a cDNA vector containing a full-length MUM-1 open reading frame. The open reading frame contains at least two restriction endonuclease sites, as shown. The presence of these two sites indicates the division of the MUM-1-encoding cDNA into three fragments, each encoding a MUM-1 fragment. Accordingly, applicant maintains that the phrase "a fragment thereof" is supported by the application as filed, and that therefore, the September 17, 2001 Amendment satisfies the provisions of 35 U.S.C. §132.

Riccardo Dalla-Favera
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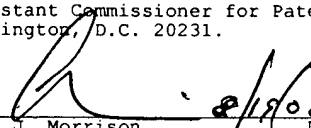
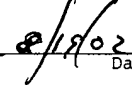
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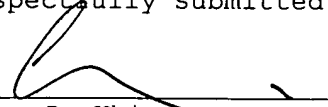
In view of the arguments set forth above, applicant maintains that the Examiner's objections and rejections have been overcome, and respectfully requests that he reconsider and withdraw same.

If a telephone conference would be of assistance in advancing the prosecution of the subject application, applicant's undersigned attorneys invite the Examiner to telephone them at the number provided below.

No fee, except for the \$55.00 fee for a one-month extension of time, is deemed necessary in connection with the filing of this Communication. However, if any additional fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:	
Assistant Commissioner for Patents, Washington, D.C. 20231.	
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